Report to Congress on National Coverage Determinations For Fiscal Year 2003

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This report, along with its attachments, constitutes the third annual report to Congress on Medicare national coverage determinations (NCDs) for the Centers for Medicare & Medicaid Services (CMS). As required by the Benefits Improvement and Protections Act of 2000 (BIPA 2000), we are reporting on the time required to complete and fully implement NCDs in the previous fiscal year for medical items and services not previously covered by the Medicare program. Attachment 1 provides a timeline and detailed compilation of the time necessary to complete and fully implement such NCDs made between October 1, 2002 and September 30, 2003. Attachment 2 presents similar information in a table format, including a summary of the time required to make and implement the necessary coverage, coding, and payment determinations for each NCD.

Six NCDs were published and implemented in FY 2003 that expanded coverage for medical items and services not previously covered by the Medicare program. The average time needed to issue a decision memorandum was 353 days. The average time needed to issue and implement an NCD was 461 days. These averages reflect not only the straightforward determinations from FY 2003, but also determinations that may have required an external technology assessment (TA) referral, a Medicare Coverage Advisory Committee (MCAC) recommendation or both. Significant steps in the NCD process that impact the general 90-day target time are described in the chart below.

We published a notice on April 27, 1999 (64 FR 22619) announcing a new process for making NCDs. As part of that process, a series of internal time frames to enhance the accountability of the NCD development process were established. The process described in that notice improves the coverage process by making it more open and responsive. The process balances the need for thorough and consistent review of evidence with the need for timely determinations. Each NCD often requires a comprehensive technology assessment to examine the potential impact of the item or service on the health outcome. The time frames from the 1999 notice are those generally necessary to respond to a relatively straightforward coverage issue. A significantly more complex or controversial coverage issue may require an extension of these time frames.

We recently published a notice on September 26, 2003 (68 FR 55634) that supplements the April 1999 notice. This notice became effective on October 27, 2003 and revises the process we use to make a national coverage determination. One improvement is the establishment of a two-way track for the initial NCD request. One track is a highly time-structured track only available to aggrieved parties. The other track is open to anyone, and offers a more collaborative and less time-stringent process. The notice also clarifies the conditions for acceptance of a complete, formal request as well as defining what does not constitute a complete request. We revised our process for developing an NCD in order to make the process more efficient and ensure that we have access to all relevant information to make fully informed decisions.

Section 731 of the Medicare Modernization Act has altered our procedures for making national coverage determinations. Those changes increase the opportunity for public

participation by permitting comments on a proposed decision memorandum. The full impact of those changes will be reflected in future reports.

The critical steps in the development process include the length of time necessary to make a determination with and without the commission of a technology assessment (TA) or referral to the Medicare Coverage Advisory Committee (MCAC), and the time necessary to implement the determination. The chart below maps out the targets (as designated in the April 1999 and October 2003 notices) and the average time for each significant step in the NCD process for the six NCDs included in this report, measured in calendar days.

Significant Steps in the Completion of a NCD

	TARGET TIME (in days)	AVERAGE TIME (in days)
Days to a Determination without a TA and/or MCAC	90	199
Additional Days to a Technology Assessment	180	122
Additional Days to MCAC recommendation	180	155
Days to implement decision (from date of decision memorandum)	180-270	108

The NCD review process often requires an external TA. An external TA is requested if the scope and magnitude of the subject are too extensive to be reviewed internally. Generally, the anticipated completion date for a TA is 180 days. Once received, the completed TA is posted to our website.

The MCAC is used to supplement our internal expertise and obtain public input and participation in our consideration of "state of the art" technology, science, and medicine. The MCAC is advisory in nature, with the final decision on all issues resting with us. It is chartered under the Federal Advisory Committee Act (FACA). Significant time in the MCAC review process is necessary to comply with FACA administrative requirements. Under FACA, each MCAC member must undergo an initial conflict of interest clearance process. Each member, prior to serving at a meeting, is further reviewed to ensure that they do not have any financial interests that conflict with the specific issue being referred to the MCAC.

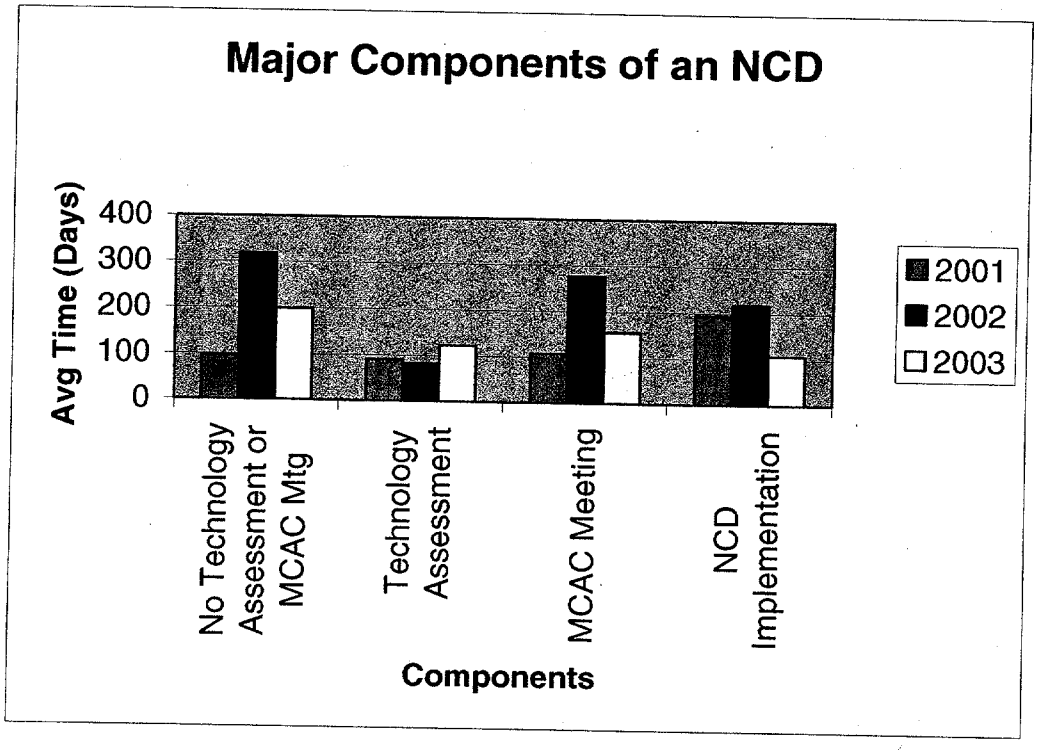
The MCAC is comprised of up to 100 members with diverse scientific and medical backgrounds. No more than fifteen members serve at any one meeting. An issue is reviewed and discussed at the MCAC meeting in a public forum. The MCAC develops specific recommendations. The recommendations are then forwarded to us for consideration in making a national coverage determination. Prior to the most recent Charter amendment, the MCAC was comprised of six specialty panels and an Executive Committee (EC). The EC had to ratify the recommendations of the panels before

forwarding their recommendations to CMS. The recent change to the Charter to eliminate the need for the EC ratification process will reduce the average time to complete an NCD and MCAC by 2-3 months.

The Implantable Cardioverter Defibrillators (ICDs) determination is an example of the revised Charter accelerating the MCAC review process. The total number of days from the initial referral to the MCAC and the posting of the meeting minutes was 138 days, approximately 323 days less than the average time to receive an MCAC recommendation reported in the FY 2002 Report to Congress. The overall time to the decision memorandum was less because the new MCAC structure allowed for the MCAC to communicate its' recommendations directly to CMS, rather than through the EC which would have added an additional 2-3 months to the process.

For the time period covered by this report, we issued a decision memorandum within 60 calendar days of receiving the final report from a technology assessment or MCAC recommendation. The decision memorandum merely announced our intention to make a national coverage determination (NCD). This informed the public of our prospective policy while the implementation phase was completed. The actual NCD was issued within 60 calendar days of announcing an effective/implementation date after the release of the decision memorandum.

The graph below illustrates the average time necessary to complete each of the significant steps in the NCD process since the implementation of BIPA and the creation of this report. Between 2002 and 2003, we have made considerable improvement in the completion of three of the four steps. For the fourth step, the average time necessary to complete a technology assessment increased slightly in 2003, however it is still below the target time of 180 additional days.



Attachment 1 offers a time line of actual dates for each significant step and a brief summary of the NCD. The time line spans the period from the date of initial request to the date of implementation, capturing all the significant dates along the way; i.e., acceptance of the initial request, posting of the decision memorandum, publication of the instructions, and implementation of the decision. For those NCDs where a TA was obtained and/or the MCAC was consulted, Attachment 1 also includes receipt date of the TA, date of referral to the MCAC, and date of receipt of the final MCAC recommendations. Also included are the numbers of calendar days from the date of request to date of the decision memorandum, date of decision memorandum to date of implementation, and total number of days from date of request to date of implementation.

Attachment 2 is a tabular summary of the NCDs and related information. It charts the NCDs along with the periods of elapsed time measured in calendar days for each significant step within the coverage process. The chart contains six columns for each completed NCD. The first column represents the time elapsed from the date of acceptance to the date the decision memorandum was posted to our website for public display. The next two columns document time needed to obtain a TA and referral to the MCAC. Not all issues require an external TA or a referral to the MCAC. However, if either of these routes is chosen to assist in the NCD process, they do extend the time it takes to implement an NCD. Therefore, the columns "Days to Technology Assessment" and "Days to MCAC Recommendation" represent the time elapsed from date of acceptance to either the date of receiving the TA or the date of receiving the signed MCAC recommendation.

Attachment 2 also factors in coding; publication of the instructions, and implementation, all of which took place after the decision memorandum had been published. The number of days to publication of the instructions and implementation is calculated from the date the decision memorandum was published. A column is included to indicate that a new code was created for payment and claims submission. However, not all NCDs require a new code. Coding does not signify coverage, but occurs simultaneously with publication of the contractor instructions. Therefore, if it was necessary to create a new code or modify an existing code, this step in the process also added to the time required to implement an NCD.

The last column of Attachment 2 represents the total elapsed time from the date of the decision memorandum to the date of implementation. If a decision is made to cover an item or service, frequently claims processing instructions must be developed and issued to our contractors to ensure accurate payment and consistent claims processing. We have a contractual agreement with our contractors to provide five months lead time for any systems changes to ensure accuracy and consistency among our contractors. Generally, we made payment changes effective within 180 calendar days of the first day of the next full calendar quarter that follows the date the NCD was issued. Not all NCDs require systems changes. However, if systems changes are necessary, this also adds to the time required to implement an NCD.

Aside from the six NCDs noted in the report as fully implemented in FY 2003, we also made two decisions that were announced to the public via decision memorandum during

FY 2003. However, because of the time necessary to complete the payment and coding phases of implementation, two NCDs did not become fully operational by the September 30, 2003, cut-off for this report and will be cited in the report for FY 2004. (In addition to the NCDs included in this report that expanded coverage, we also implemented seven NCDs in FY03 that clarified the perimeters of coverage and updated codes described in current coverage policies.)

Five decisions were noted in last year's report for FY 2002 that did not qualify for inclusion under the strict interpretation of BIPA 2000. They were announced to the public via decision memorandum in FY 2002. However, due to the time necessary to complete payment and coding, they were not implemented until FY 2003. Within the spirit of the law, information on those five decisions is included in brief summary below. Publication of the instructions and implementation of the decision were the only steps that fell outside the criteria for inclusion in the FY 2002 report. All five decisions expanded coverage of medical items and services not previously covered by Medicare. The five decisions, the number of days to the decision memoranda, and the number of days to implement the decision memoranda is listed below:

National Coverage Determinations	**Days From Request To Decision Memorandum**	**Days From Decision Memorandum To Implementation**
Neuromuscular Electrical Stimulation (NMES) for Spinal Cord Injuries	94	253
Electrical Stimulation for Wounds	694	252
Levocarnitine for End Stage Renal Disease	460	163
Hyperbaric Oxygen (HBO) Treatment for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities	639	214
Home Blood Glucose Monitors	63	67

Occasionally, national coverage requests are put on hold so that the requestor can augment their initial formal request with new or additional information. Since these requests for postponement are not initiated by CMS, this type of delay was not considered in the development of target times for an NCD published in the 1999 Federal Register notice. Therefore, it does add significant time to the ultimate completion of the decision memorandums. Levocarnitine for End Stage Renal Disease and Hyperbaric Oxygen (HBO) Treatment for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities are examples of issues that encountered such a delay.

The Levocarnitine request was originally accepted on April 18, 2001 but additional time was necessary to complete the review especially when new material was accepted on June 21, 2002. Also, the HBO request was originally accepted on November 29, 2000 but on January 17, 2002, we received a letter from the requestors asking us to expand the original request for HBO treatment of hypoxic wounds, to include, more specifically,

treatment of diabetic wounds of the lower extremities. This extended the due date to 90 days after receipt of the additional information from the requestor. On April 29, 2002 the deadline was extended again to allow additional time to review new material submitted by the requestor.

Similarly, the decision for Electrical Stimulation for Wounds was delayed until a pending court case was completed. The decision memorandum was prepared but not released until the court ruling was issued. Since this delay was outside the perimeters of our self-imposed target times, it added significant time to the completion of the NCD.

We are continually improving the NCD process so appropriate new technologies are covered under Medicare as quickly as possible. As noted earlier, the recent changes to the Charter of the MCAC help streamline the NCD process. Also, other enhancements to the NCD process were recently announced in the September 26, 2003 publication of the Federal Register.

That notice illustrated the changes developed to improve the timeliness of the NCD process. It included a clear definition of a complete request. An NCD request will only be accepted when it has met all of the criteria outlined in this notice and is considered a complete and formal request. This will eliminate the need for delays in the process to gather additional information. Previously, some NCDs went beyond our self-imposed timeframes because of incomplete requests. The 90-day timeframe began once the request was accepted, regardless whether or not it was complete. That notice set forth our effort to make the NCD process more efficient, while maintaining an open process.

In addition, the NCD for Deep Brain Stimulation (DBS) for Parkinson's Disease illustrates our efforts to improve the NCD process through collaboration with agencies outside CMS. We collaborated with FDA during the pre-approval phase of the device to expedite the review process. We worked in parallel by accepting the request and initiating our review nearly three months before the FDA approval. During this time, we remained in close contact with the requestors in order to expedite the complete formal coverage request once it received FDA approval.

In 2003, the Implantable Cardioverter Defibrillators (ICDs) NCD illustrates improvements to the NCD process. While the target time to implement a decision is 270 days, ICDs was implemented in 117 days. This reduction in time is due to detailed coordination between two integral components within CMS. CMM and CAG were working simultaneously on the instructions during the review process to expedite implementation. The integral coordination between these internal components allowed for an NCD to be issued in a more timely and efficient manner.

Some of the NCDs included in next year's report will have been completed under the newly revised NCD process established by Section 731 of the Medicare Prescription Drug and Modernization Act (MMA), effective January 1, 2004. Under the MMA, the proposed coverage decision will be made public within 6 months of the date of the request (for an NCD not requiring a technology assessment or MCAC review). However, if the NCD requires a TA or MCAC review, the draft coverage decision will be made public within 9 months. Following the publication of the proposed decision, there will be

a 30-day public comment period, and a final decision is then made and implemented within 60 days of the close of public comments. For example, the recent decision for Positron Emission Tomography (PET) for Alzheimer's Disease/Dementia was completed and implemented under the MMA timelines.

The MMA also requires the Secretary to make public, the factors and timelines considered in making NCDs (i.e. whether an item or service is "reasonable and necessary" for Medicare beneficiaries. NCD guidance documents will be developed in a manner similar to that used for Food and Drug Administration (FDA) guidance documents. The process for issuing NCD guidance documents was issued as a Federal Register Notice on September 24, 2004.

National Coverage Determinations (NCDs) can take a number of forms. They can be absolute, and cover or not cover medical items or services; can leave coverage determinations of medical items and services subject to local carriers; or most often, make coverage determinations with limitations indicating clinical conditions, demographic information, etc... that place evidence-based boundaries on coverage. This list includes only the NCDs the Centers for Medicare & Medicaid Services (CMS) published in Fiscal Year 2003 that expanded Medicare benefits to medical items or services not previously covered by Medicare.

The following completed NCDs reached under the term of the new coverage process are posted on the CMS website at http://www.cms.gov/coverage/default.asp.

1. Serum Iron Studies for Anemia Caused by Sickle Cell or End-Stage Renal Disease (ESRD)

From date of request to date of determination, 85 days; From date of determination to date of implementation, 63 days; 148 days overall.

On January 28, 2003, CMS issued a decision memorandum to add the following ICD-9-CM codes to the list of ICD-9-CM codes covered by Medicare under the Serum Iron Studies NCD: 282.60, 282.61, 282.62, 282.63, 282.69, and 285.21.

TIMELINE:

11/04/2002	Request Accepted
1/28/2003	Decision memorandum posted
2/28/2003	Published Instructions
4/01/2003	Implemented Decision

2. Deep Brain Stimulation (DBS) for Parkinson's Disease

From date of request to date of determination, 475 days; From date of determination to date of implementation, 54 days; 529 days overall.

On February 6, 2003, CMS issued a decision memorandum to cover *unilateral or bilateral thalamic VIM DBS* for the treatment of essential tremor (ET) and/or Parkinsonian tremor and *unilateral or bilateral STN or GPi DBS* for the treatment of Parkinson's disease only under the conditions outlined in the decision memorandum.

TIMELINE:

10/19/2001	Request accepted
2/02/2002	Technology Assessment received
6/12/2002	MCAC Medical and Surgical Procedures Panel meeting
9/25/2002	MCAC Executive Committee ratified panel recommendations
11/01/2002	Received MCAC signed minutes
2/06/2003	Decision memorandum posted
2/14/2003	Published Instructions
4/01/2003	Implemented Decision

3. Magnetic Resonance Angiography (MRA) of the Abdomen and Pelvis

From date of request to date of determination, 288 days; From date of determination to date of implementation, 77 days; 365 days overall.

On April 15, 2003, CMS issued a decision memorandum to expand coverage of MRA to include imaging the renal arteries and the aortoiliac arteries in the absence of abdominal aortic aneurysm or aortic dissection.

TIMELINE:

7/01/2002	Request accepted
4/15/2003	Decision memorandum posted
5/09/2003	Published Instructions
7/01/2003	Implemented Decision

4. Positron Emission Tomography (FDG-PET) for Thyroid Cancer

From date of request to date of determination, 672 days; From date of determination to date of implementation, 168 days; 840 days overall.

On April 16, 2003, CMS issued a decision memorandum to cover the use of FDG PET for staging of thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation with an elevated or rising serum Tg > 10 ng/ml and negative I-131 WBS.

TIMELINE:

6/13/2001	Request Accepted
4/15/2002	Technology Assessment received
9/25/2002	MCAC Executive Committee discussed reviewing evidence for rare conditions
11/01/2002	Received MCAC signed minutes
4/16/2003	Decision memorandum posted
6/20/2003	Published Instructions
10/01/2003	Implemented Decision

5. Positron Emission Tomography (n-13 Ammonia) for Myocardial Perfusion

From date of request to date of determination, 224 days; From date of determination to date of implementation, 168 days; 392 days overall.

On April 16, 2003, CMS issued a decision memorandum to cover the use of N-13 ammonia PET for the evaluation of myocardial perfusion under the following conditions: the PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or the PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive.

TIMELINE:

9/04/2002	Request Accepted
4/16/2003	Decision memorandum posted
6/20/2003	Published Instructions
10/01/2003	Implemented Decision

6. Implantable Cardioverter Defibrillators (ICD)s

From date of request to date of determination, 372 days; From date of determination to date of implementation, 117 days; 489 days overall.

On June 6, 2003, CMS issued a decision memorandum to cover ICDs for patients with a documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause; Documented sustained ventricular tachyarrhythmia, either spontaneous or induced by an electrophysiology (EP) study, not associated with myocardial infarction (MI) and not due to a transient or reversible cause; Documented familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmias, such as long QT syndrome or hypertrophic cardiomyopathy; or coronary artery disease with a documented prior myocardial infarction, a measured left ventricular ejection fraction < 0.35, and inducible, sustained ventricular tachycardia (VT) or VF at EP study.

TIMELINE:

5/30/2002	Request accepted
2/12/2003	MCAC meeting[1]
4/01/2003	Received MCAC signed minutes
6/06/2003	Decision memorandum posted
8/25/2003	Published Instructions
10/01/2003	Implemented Decision

[1] The February 12, 2003 MCAC meeting was convened under a new MCAC charter (signed by the Secretary on November 22, 2002) which revised the existing MCAC structure so that the MCAC could send its recommendations directly to CMS, and eliminated the need for an additional MCAC Executive Committee meeting.

The significant steps in the completion of a national coverage decision described in this chart are "snapshots" of time in the process that can overlap, as they often happen concurrently. The chart reflects the distinct time periods, pre-decisional and post decisional, that influence the completion of a decision. A key to the chart is included on page 2 to define the specific time intervals described.

	Pre-Decision			Post-Decision			
	Days to Technology Assessment (TA)[2]	Days to MCAC Recommendation[3]	Days to Decision[1]	New Code Created[4]	Days to publication of Instructions[5]	Days to Implement Decision[6]	Total Days Overall
Decisions subject to 90 daytimeline (no TA and no MCAC recommendations required)							
Serum Iron Studies for Anemia caused by Sickle Cell or End Stage Renal Disease (ESRD)	n/a	n/a	85	no	31	63	148
Magnetic Resonance Angiography (MRA) of the Abdomen and Pelvis	n/a	n/a	288	no	24	77	365
Positron Emission Tomography (n-13 Ammonia) for Myocardial Perfusion	n/a	n/a	224	no	65	168	392
Decisions Subject to 180 dayTA Timeline and 180 day timeline for MCAC recommendation[7]							
Deep Brain Stimulation (DBS) for Parkinson's Disease	51	238	475		8	54	529
Positron Emmision Tomography (FDG-PET) for Thyroid Cancer	193	137	672		65	168	840

Decisions Subject to 180 dayTA Timeline and 180 day timeline for MCAC recommendation[7]	Pre-Decision			Post-Decision			
	Days to Technology Assessment (TA)[2]	Days to MCAC Recommendation[3]	Days to Decision[1]	New Code Created[4]	Days to publication of Instructions[5]	Days to Implement Decision[6]	Total Days Overall
Implantable Cardioverter Defibrillators (ICD)s	n/a	90	372	no	80	117	489

[1] calendar days elapsed from date of acceptance of request to date of decision memorandum posted on CMS website. April 27, 1999 notice (64 FR 22619) self-imposed a 90 day timeline for those decisions not obtaining a TA or consulting MCAC.

[2] calendar days elasped from date of request of technology assessment to date of receipt of technology assessment. April 27, 1999 notice (64 FR 22619) self-imposed a 180 day timeline for the completion of a technology assessment used in a coverage decision.

[3] calendar days elasped from date of request of MCAC review to date of receipt of signed minutes from MCAC executive committee. April 27, 1999 notice (64 FR 22619) self-imposed a 180 day timeline for the receipt of recommendations from MCAC.

[4] whether decision resulted in creation of new code

[5] calendar days elapsed from date of decision memorandum posted on website to date of publication of instructions

[6] calendar days elapsed from date of decision memorandum posted on website to date of implementation of instructions (effective date). April 27, 1999 notice (64 FR 22619). Notice outlines timeline stating "Generally, CMS will make payment changes effective within 180 calendar days of the first day of the next full calendar quarter that follows the date the NCD is issued". (180-270 days range)

[7] calendar days elapsed from date of acceptance of request to completion of decision memorandum (self-imposed timeframe is 450 days).